510(k) SUMMARY **Date Prepared: September 11, 2000**

SEP 1 9 2000 K002837

Company Name and Address

Aspect Medical Systems, Inc.
141 Needham St.
Newton, MA 02464

Contact Person: Christine M. Vozella
Director, Regulatory Affairs/Quality Assurance

Device Name

Proprietary Name: BIS Engine (PCB component in an EEG Monitor)
Common Name: EEG Monitor

Classification

Electroencephalograph (EEG) monitors and their software have been classified by the Neurological Devices Panel as Class II devices (21 CFR 882.1400)

Predicate Device

Aspect A-2000 EEG BIS Monitor, 510(k)# K974496 (with BIS Engine), FDA cleared 2/6/98

Device Description

The Aspect Medical Systems, Inc. BIS Engine provides the means for incorporating Aspect's proprietary BIS technology into OEM (other equipment manufacturer's, i.e. our business partner's) finished devices. It is a small printed circuit board (PCB) that can either reside inside the OEM finished device or is re-designed for smaller size and packaged in a housing that will connect to the OEM finished device. OEMs (our business partners) are responsible for determining regulatory pathways/510(k) Notifications as it relates to their finished device.

The BIS Engine allows for 2 channel maximum EEG monitoring, and is indicated for use in monitoring the state of the brain by data acquisition of EEG in the intensive care unit, operating room and for clinical research. The BIS (Bispectral Index) is also indicated as an aid in monitoring the effects of certain anesthetic agents.

The fundamental scientific technology has not changed. The BIS technology remains the same. The BIS Engine (subject of this 510(k)) has the same basic function, and same operating principal as the Predicate device's BIS Engine.

Intended Use

Intended to monitor the state of the brain by data acquisition of EEG signals in the intensive care unit, operating room and for clinical research.

The BIS, a processed EEG variable, may be used as an aid in monitoring the effects of certain anesthetic agents.

K002837

Summary of Technological Characteristics Compared to Predicate Device

Similarities

The indications for use are the same. The fundamental technology has not changed. The BIS technology remains the same. The BIS Engine has the same basic function, same operating principal, and same signal processing. Timing of processes, handling of error messages, handling self tests, and DSC communication remain the same. The DSP processor has the same instruction set.

The same information will be supplied to each business partner, i.e. BIS index, EMG, etc. In addition, the same user features will be available to each OEM business partner, and the choice is dependent on their individual requirements.

Minor Differences

The Predicate device BIS Engine is composed of the FPGA, Flash Memory, RAM, DSP, while the modified BIS Engine is composed of all the electronic components mentioned above, and in addition, the RS-232 drivers.

The source code differs in that there are additional commands and additional messages that have been incorporated due to the changes in the electronic components mentioned above.

Software functionality is similar, although the BIS Engine has additional functionality that is handled by the host processor in the Predicate device.

The BIS Engine FPGA communicates with the business partner's remote host processor through optional RS-232 drivers. The predicate device FPGA communicates directly with the host processor, which resides within the Predicate device.

As this is a component of a larger system, power is supplied by the remote host.

The DSP processor is similar in that it has the same instruction set, but is faster, smaller and consumes less power.

The following analysis/verification/validation was performed:

Risk analysis
Software validation
Electronic verification
Mechanical/environmental validation

There are no additional hazards or risks introduced by the modified BIS Engine. The applicable testing was completed. Test results are acceptable.

The BIS Engine is substantially equivalent to the Predicate device's BIS Engine.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 9 2000

Ms. Christine M. Vozella
Director, Regulatory Affairs/Quality Assurance
Aspect Medical Systems, Inc.
141 Needham Street
Newton, Massachusetts 02464-1505

Re: K002837
Trade Name: Aspect Medical Systems, Inc. BIS Engine
Regulatory Class: II
Product Code: GWQ
Dated: September 11, 2000
Received: September 12, 2000

Dear Ms. Vozella:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K002837

Device Name Aspect Medical Systems, Inc. BIS Engine

Indications for Use

Intended to monitor the state of the brain by data acquisition of EEG signals in the intensive care unit, operating room and for clinical research.

The BIS, a processed EEG variable, may be used as an aid in monitoring the effects of certain anesthetic agents.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lochner

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002837

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)